OCT 2 7 2000

510(k) Summary

K002424

Date:	August 3, 2000
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Diana Thorson, Regulatory Affairs Specialist, (714)730-5000, Extension 4121
Device Proprietary Name:	3D Angiographic Imaging System, Model XIDF-100A
Classification Name:	Image Intensified Fluoroscopic X-Ray System (Accessory)
Common Name:	Image Processor [Fed. Reg. No. 892.1650, Product Code: JAA]
Predicate Device:	GE Advantage 3D XR (K974715)
Reason for Submission	New option for existing product

Description of this Device:

The 3D Angiographic Imaging System, Model XIDF-100A is an option for the Toshiba Infinix VC, NS, and NB Angiography Systems. The image processor receives two dimensional rotational DSA images acquired by the angiography system, transforms them into three dimensional images, and transmits them to a 3D workstation for viewing.

Summary of Intended Uses:

This system is designed to be used in combination with Toshiba Infinix VC, NS, and NB Angiography Systems, and a 3D Workstation. The image processor receives two dimensional rotational DSA images acquired by the angiography system, transforms them into three dimensional images, and transmits them to a 3D workstation for viewing. The system is intended to support interventional radiology techniques. This device employs no intended uses that are not in cleared devices already found in the marketplace.

Technological Characteristics:

The technological characteristics of this device are the same as that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Diana Thorson
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
P.O. Box 2068
Tustin, CA 92781-2068

Re: K002424
3D Angiographic Imaging System,
Model XIDF-100A
Dated: August 3, 2000
Received: August 8, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Thorson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510 (k) Number (If Known): K002424

Device Name: Toshiba 3D Angiographic Imaging System, Model XIDF-100A

Indications For Use:

This system is designed to be used in combination with Toshiba Infinix VC, NS, and NB Angiography Systems, and a 3D Workstation. The image processor receives two dimensional rotational DSA images acquired by the angiography system, transforms them into three dimensional images, and transmits them to a 3D workstation for viewing. The system is intended to support interventional radiology techniques.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-the-Counter Use _____

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510 (k) Number: K002424